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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Gerald R. Heller

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SUITE 800

MINNEAPOLIS, MN 55403-2420

EXAMINER

VU, QUYNH-NHU HOANG

ART UNIT

PAPER NUMBER

3763

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/763,932

Applicant(s)

HELLER ET AL.

Examiner

QUYNH-NHU H. VU

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 January 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10-13, 15-18 and 23-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10-13, 15-18, 23-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SF/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Response to Amendment

Amendment filed on 1/30/09 has been entered.

Claims 10, 13, 15-18, 23-30 are present for examination.

Claim 31 is withdrawn.

Claims 1-9, 14, 19-22 are cancelled.

Election/Restrictions

Newly submitted method claim 31 is directed to an invention that is distinct from the invention originally claimed for the following reasons: The device claims do not need to performing step of method as in method claim 31.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 31 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

It is noted that Examiner believes that device claims 10-13, 15-18, 23-26 and method claims of claims 27-30 are not patentable distinguish from each other. Therefore, claims 10-13, 15-18, 23-26, 27-30 are examined together because the method of these steps in claims 27-30 must be performed in order to obtain the device of claims 10-18, 23-26. The device claims do not need to performing step of method in claim 31, therefore, Examiner will not examine claim 31.

However, if Applicant does not agree the claims 1 and 33 are not patentable distinguishable, then the claims would be subject to further Election/Restriction.

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "a sheath extending about the catheter and covering said stent" of claim 17; the limitation "a second adapter having an outer diameter substantially equal to

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the inner diameter of the catheter" of claim 23 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Terminal Disclaimer

The terminal disclaimer filed on 1/30/09 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Specification

The disclosure is objected to because of the following informalities: there is no description of Fig. 6 under BRIEF DESCRIPTION OF THE DRAWING.

Appropriate correction is required.

Claims 17, 23-30 are objected to because of the following informalities: there is no where show the limitations that: a sheath extending about said catheter and covering said stent (claim 17); a second adapter having an outer diameter substantially equal to the inner diameter of the catheter and a second inner diameter (claims 23-30). According to Figs. 1-5, there is only one adapted 39 provided in the catheter system 11. Appropriate correction is required.

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Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 17, 23-30 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In claim 17, nowhere in the Specification shows that: a sheath extending about the catheter and covering said stent.

In claims 23-30, the limitation "a second adapter having an outer diameter substantially equal to the inner diameter of the catheter and a second inner diameter" is not consistency with the Figs. 1-5. According to Figs. 1-5, they only show that there is only one adapter 39 provided in the catheter system 10.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 10-12, 23-30 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Stevens (US 4,798,586).

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Regarding claims 10-12, Stevens discloses a catheter system comprising: a drive catheter 30 is substituted for the first guide wire 20 (col. 4, lines 9-10); wherein the first guide wire having a first external diameter; a second wire 64 is considered as a guide wire having a second external diameter smaller than the first external diameter.

A catheter 10 including a lumen defining an internal diameter substantially equal to the first external diameter of the first guide wire for fitting accommodation thereof;

Wherein the catheter includes a balloon 11 portion; and an adapter (including 10b and 60 in Figs. 6-7 or 90 in Figs. 8-10) positionable within the lumen of the catheter, the adapter including an external diameter substantially equal to the internal diameter of said lumen of the catheter, said adapter further including a lumen defining an internal diameter substantially equal to said second external diameter of said second guide wire for fitting accommodation thereof.

Regarding claims 23-26, Stevens discloses a catheter system comprising: a catheter 10 having an inner diameter; a guide wire 20 is extending through the catheter. As noted that, the drive catheter 30 is substituted for the guide wire 20, col. 4, lines 9-10. The guide wire having an outer diameter;

a first adapter (including 10 and 60) having an outer diameter substantially equal to the inner diameter of the catheter 10 including a balloon and a first inner diameter;

a second adapter 80 having an outer diameter substantially equal to the inner diameter of the catheter and a second inner diameter;

wherein the first inner diameter of first adapter is substantially equal to the outer diameter of the guide wire. In other words, the guide wire 20 substantially fit into the first adapter 60;

wherein the second inner diameter of second adapter is different from the first inner diameter of first adapter; and

where in the first adapter is disposed between the catheter and the guide wire.

Regarding claims 27-30, since the method of configuring or performing a catheter system is merely a list of steps of using configuring a catheter system, these steps must be performed in order to

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obtain the device (see rejection of claims 10-13, 15-18, 23-26 above). Therefore, the method for configuring a catheter system would be inherent to the shown structure of the device.

Claim 13 is rejected under 35 U.S.C. 103(a) as unpatentable over Stevens (US 4,798,586) in view of Donadio, III et al. (US 5,741,429).

Stevens discloses the claimed invention except for that a portion of the adapter extending beyond the length of the catheter includes a flexible tapered tip.

Donadio discloses, Figs. 12-13, a catheter system comprising: a guide wire 95; a catheter 20 (col. 6, lines 26-29) including a lumen defining an internal diameter; an adapter (including 96 and 93) selective position able within the lumen of the catheter, the adapter is removable slidably within the lumen of the catheter.; wherein the adapter extends beyond the length of the catheter, the portion extending beyond the catheter being adjustable by slidably positioning the adapter within the lumen of the catheter (Figs. 12-13); the portion 93 of the adapter extending beyond the length of the catheter includes a flexible tapered tip (Figs. 12-13).

It would have been obvious at the time the invention was made to a person having ordinary skill in the art to modify the device of Stevens with a flexible tip, as taught by Donadio, in order to provide the flexible during its insertion and prevent damage the blood vessel tissue

Claims 15-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stevens in view of Leoffler (US 5,891,154).

Stevens discloses the invention substantially as claimed. Stevens does not disclose the catheter includes a radially expandable stent.

Leoffler discloses a catheter includes a stent 16 positioned about an expandable balloon portion 14. Also, it is well known in medical art, especially in percutaneous transluminal coronary angioplasty (PTCA) that the catheter includes an expandable stent to expand and hold the damaged artery.

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It would have been obvious at the time the invention was made to a person having ordinary skill in the art to modify the device of Stevens with a stent, as taught by Loeffler, in order to expand and hold the damaged artery.

Claims 17-18 are rejected under 35 U.S.C. 103(a) as obvious over Stevens.

Regarding claim 17, as best as understood, Stevens discloses the claimed invention except for that a sheath extending about the catheter and covering the stent. However, it is well-known in the art to provide a sheath covering the catheter/introducers are used to provide a conduit for introducing catheter, fluids or other medical devices into blood vessels. For example: the outer catheter is considering as a sheath and covering the inner catheter is very well-known in the catheter art.

Regarding claim 18, Stevens discloses the claimed invention except for the lumen of the catheter is about 0.0035 inches and the lumen of the adapter is about 0.018 inches. It would have been obvious to one having ordinary skill in the art at the time of the invention was made to provide the values listed above, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to QUYNH-NHU H. VU whose telephone number is (571)272-3228. The examiner can normally be reached on 6:00 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nicholas D Lucchesi/
Supervisory Patent Examiner, Art Unit 3763

Quynh-Nhu H. Vu
Examiner
Art Unit 3763